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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,432	03/20/2001	Raymond J. Taupier JR.	15966-729 (Cura-229)	3506

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Ivor R. Elrifi
MINTZ, LEVIN, COHN, FERRIS
GLOVSKY and POPEO, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
EINSMANN, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/21/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,432	TAUPIER ET AL.	
	Examiner	Art Unit	
	Juliet Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29, and 32, drawn to isolated polypeptides, classified in class 530, subclass 350.

II. Claims 5-14, 30, and 33, drawn to isolated nucleic acids, vectors, and host cells, classified in class 536, subclass 23.1, for example.

III. Claims 15-17, 31, and 34, drawn to isolated antibodies, classified in class 530, subclass 387.1.

IV. Claim 18, drawn to methods for determining the presence of a polypeptide, classified in class 435, subclass 7.1.

V. Claims 19 and 41, drawn to methods for detecting the presence of a nucleic acid and/or predisposition to disease which utilized detection of nucleic acids, classified in class 435, subclass 6.

VI. Claim 20, drawn to methods for identifying a binding agent that binds a polypeptide, classified in class 436, subclass 501.

VII. Claim 21, drawn to methods for identifying a potential therapeutic agent for use in treatment, classified in class 436, subclass 501.

VIII. Claims 22, 27-28, and 43, drawn to methods for modulating polypeptide activity or treating pathology utilizing antibodies, classified in class 424, subclass 130.1.

IX. Claims 23-24 and 42, drawn to methods of treating pathology comprising administering a polypeptide of claim 1, classified in class 514, subclass 2.

X. Claims 25-26, drawn to methods of treating pathology comprising administering a nucleic acid, classified in class 514, subclass 44.

XI. Claim 35, drawn to a method of manufacturing a medicament utilizing a polypeptide, classified in class 514, subclass 2.

XII. Claim 36, drawn to a method of manufacturing a medicament utilizing a nucleic acid, classified in class 514, subclass 44.

XIII. Claim 37, drawn to a method of manufacturing a medicament utilizing an antibody, classified in class 424, subclass 130.1.

XIV. Claims 38-40, drawn to methods of screening for modulator activity, classified in class 436, subclass 501.

Further Restriction Applicable to All Groups

Each group detailed above reads on a number patentably distinct groups, wherein each of the distinct groups is drawn to or utilizes a polypeptide or a nucleic acid represented by a distinct SEQ ID NO. Applicants must further elect a single SEQ ID NO for examination with whichever claim set is elected. For example, if applicant elects the polypeptide claims of group I, applicant should further elect a single polypeptide sequence from those recited in claim 1.

Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims.

Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and this further restriction requirement should not to be construed as a species election.

The inventions are distinct, each from the other because of the following reasons:

2. With regard to the restriction between individual sequences, each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because they do not share a common structure. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

3. The inventions of Groups I, II, and III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group II is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group I is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups I, II, and III can be used in materially different processes, for example, the DNA of Group II can be used in hybridization assays, the antibody of Group III can be used in immunoassay, and the polypeptide of Group I can be used to make fusion protein with an enzymatic function. Although the polynucleotides and polypeptides are related as the claimed polynucleotide is asserted to encode the claimed

polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein as evidenced by the methods of at least groups V. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and are patentably distinct from each other.

4. Invention I is related to inventions IV, VI, VII, VIII, IX, XI, and XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention I can be used in a wide variety of methods, as is exemplified by the different methods of groups IV, VI, VII, VIII, IX, XI, and XIV. In addition, the polypeptides can be used for raising antibodies, for example.

5. Invention I is unrelated to inventions V, X, XII, and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions V, X, XII, and XIII do not recite the use of or require the polypeptides of invention I for practice of the claimed invention.

6. Invention II is unrelated to inventions IV, VI, VII, VIII, IX, XI, XIII, and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions IV, VI, VII, VIII, IX, XI, XIII, and XIV do not recite the use of or require the nucleic acids of invention II for practice of the claimed invention.

7. Invention II is related to inventions V, X, and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention II can be used in a wide variety of methods, as is exemplified by the different methods of groups V, X, and XII. In addition, the polynucleotides can be used for the expression of the polypeptide that they encode, for example.

8. Invention III is related to inventions IV, VIII, and XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of invention III can be used in a variety of methods, as is exemplified by the different methods of groups IV, VIII, and XIII.

9. Invention III is unrelated to inventions V, VI, VII, IX, X, XI, XII, and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions V, VI, VII, IX, X, XI, XII, and

XIV do not recite the use of or require the antibodies of invention III for practice of the claimed invention.

10. Inventions IV-XIV are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are each drawn to methods with either separate goals, utilizing different reagents and thus having different modes of operation, or different functions or effects. For example, while the methods of groups VIII-X are all drawn to methods of treatment of pathologies, each of these groups is directed towards the administration of a different therapeutic agent, and thus would have different modes of action.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XIV require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1634

June 17, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600